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APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
Gary Karlin Michelson, M.D.	)	
Serial No.: 08/354,450	)	Group Art Unit: 3301
Filed: December 12, 1994	)	Examiner: D. DeMille
For: DEVICE FOR ARTHROSCOPIC MENISCAL REPAIR	)	

BOX AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

APPEAL BRIEF

Real Party in Interest

The real party in interest is Gary Karlin Michelson, M.D. (hereinafter, the "Applicant").

Related Appeals and Interferences

There are no appeals or interferences pending which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 19-24 and 26-28 are pending.

Claims 19-24 have been rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification as originally filed, does not provide support for the invention as now claimed. In particular, the Examiner asserts that the specification does not provide support for "the height of the projection being greater than the largest

dimension of the flexible rear member," and for "the limitations discussing the spacing relative to their height."

Claims 19-27 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, claim 19 was rejected for indefiniteness regarding the term "width," and claim 24 rejected for a lack of clarity regarding the orientation of the apexes of the projections relative to the shaft.

Claims 19, 22, and 26-28 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,261,914 to Warren (hereinafter Warren '914).

Claims 20 and 21 were rejected under 35 U.S.C. § 103 as being unpatentable over Warren '914 in view of U.S. Patent No. 4,976,715 to Bays et al. (hereinafter Bays et al. '715).

Claims 23 and 24 were rejected under 35 U.S.C. § 103 as being unpatentable over Warren '914 in view of U.S. Patent No. 4,548,202 to Duncan (hereinafter Duncan '202).

Status of Amendments

An amendment under 37 C.F.R. § 1.116 is being filed concurrently herewith to amend the language of independent claim 19 to cure the Examiner's rejections under 35 U.S.C. § 112. To Applicant's knowledge, the amendment has not been acted upon by the Examiner.

Summary of Invention

The present invention in one preferred embodiment is directed to a tissue rivet 100 (page 7, lines 1 and 2; Fig. 5) for holding two pieces of tissue M (page 6, lines 7-19; Fig. 4) together and preventing movement of rivet 100 in the tissue. Rivet 100 is made

of a bioabsorbable material (page 6, lines 27-31), and comprises a single hollow shaft 112 (page 7, lines 6-8; Fig. 5) having a central longitudinal axis (page 6, line 7), a truncated conical penetration head 114 (page 7, lines 1 and 2; Fig. 5) at its front end and a flexible member 118 (page 7, line 6; Fig. 5) at its rear end 120 (page 7, line 5; Fig. 5). Flexible member 118 has a width in at least one dimension larger than the largest width of hollow shaft 112 (Fig. 5) and is sufficiently flexible so as to be capable of deforming to conform to an angle of insertion of rivet 100 into the tissue (Fig. 7) and capable of deforming so as to conform to the surface of the tissue in which rivet 100 is inserted (page 6, lines 31-33). Hollow shaft 112 has a plurality of spaced, separate, flexible projections 116 (page 7, lines 2-5; Fig. 5) extending radially from hollow shaft 112. At least one of the plurality of flexible projections 116 is capable of flexing (page 6, line 27) toward shaft 112 when being inserted in the tissue (Fig. 7). At least a portion of the flexible projections 116 extending a distance from the central axis of shaft 112 greater than the width of flexible member 118 (Fig. 5).

Rivet 100 may be used in combination with a driving means 130 (page 7, lines 9 and 10; Fig. 5) comprising a rod 132 (page 7, line 10; Fig. 5) having an outer diameter smaller than inside diameter 124 (Fig. 5) of hollow shaft 112 of rivet 100 (page 7, lines 14 and 15; Fig. 5) and an upper handle portion 131 (page 7, line 10; Fig. 5) having a diameter larger than the inside diameter of hollow shaft 112 of rivet 100 (page 7, lines 13 and 14). Rod 132 has a tapered tip 133 (page 7, line 10; Fig. 5) forming the same angle as the angle of conical penetration head 114 of rivet 100 (page 7, lines 16-19; Fig. 6), whereby when rod 132 is fitted within hollow shaft 112 of rivet 100, the surface

of tip 133 of driving means 130 forms a smooth transition with conical penetration head 114 of rivet 100 (page 7, lines 18 and 19).

The length of rod 132 from handle 131 to tapered tip 133 of driving means 130 is preferably the length of rivet 100 (page 7, lines 23-26; Fig. 6).

Preferably, tissue rivet 100 has at least five flexible projections 116 (Fig. 5). Flexible projections 116 of tissue rivet 100 are preferably positioned in a radially staggered configuration along shaft 112. In Figs. 1 and 4-7, it may be observed that the flexible projections 16, 116 are circumferentially offset from one another.

Each of flexible projections 116 has an apex measured from the central longitudinal axis (page 6, line 7) of hollow shaft 112, in which no more than two of the apexes of flexible projections 116 are in one plane perpendicular to the longitudinal axis of shaft 112 at any point along shaft 112 (Figs. 5 and 6). The maximum width of rivet 100 does not exceed the sum of the apexes to facilitate the insertion of rivet 100 through an opening in the tissue (Fig. 7) in which rivet 100 is inserted.

Preferably, flexible member 118 has a greater surface area to mass ratio than hollow shaft 112 (Fig. 5) for permitting a higher absorption rate of the bioabsorbable material (page 6, lines 27-31) of flexible member 118.

Further, flexible member 118 of rear end 120 preferably has a smaller mass than the mass of hollow shaft 112 (Figs. 5 and 6), whereby flexible member 118 at rear end 120 is absorbed prior to hollow shaft 112 so that flexible member 118 at rear end 120 does not separate from hollow shaft 112.

In another preferred embodiment, the invention is directed to a tissue rivet 100 (page 7, lines 1 and 2; Fig. 5) for holding two pieces of tissue together and preventing

movement of rivet 100 in the tissue. Rivet 100 is made of a bioabsorbable material (page 6, lines 27-31), comprising a single hollow shaft 112 (page 7, lines 6-8; Fig. 5) having a central longitudinal axis (page 6, line 7). Hollow shaft 112 has a truncated conical penetration head 114 (page 7, lines 1 and 2; Fig. 5) at its front end, and a flexible member 118 (page 7, line 6; Fig. 5) at its rear end 120 (page 7, line 5; Fig. 5). Flexible member 118 has a width in at least one dimension larger than the largest width of hollow shaft 112 (Fig. 5) and is sufficiently flexible so as to be capable of deforming to conform to an angle of insertion of rivet 100 into the tissue (Fig. 7) and capable of deforming so as to conform to the surface of the tissue in which rivet 100 is inserted (page 6, lines 31-33). Hollow shaft 112 has a plurality of spaced, separate, flexible projections 116 (page 7, lines 2-5; Fig. 5) extending radially from hollow shaft 112.

Issues

1. Whether claims 19-24 are patentable under 35 U.S.C. § 112, first paragraph, as being supported by the specification.

2. Whether claims 19-24, 26, and 27 are patentable under 35 U.S.C. § 112, second paragraph, as being definite.

3. Whether claims 19, 22, and 26-28 are patentable under 35 U.S.C. § 103 over Warren '914.

4. Whether claims 20 and 21 are patentable under 35 U.S.C. § 103 over Warren '914 in view of Bays et al. '715.

5. Whether claims 23 and 24 are patentable under 35 U.S.C. § 103 over Warren '914 in view of Duncan '202.

Grouping of Claims

Applicant submits that the claims do not stand or fall together since each claim is separately patentable as will be explained in the Argument section below.

Argument

The Applicant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

(I) Claim Rejections Under 35 U.S.C. § 112, First Paragraph

With respect to the rejection of claims 19-24 under 35 U.S.C. § 112, first paragraph, the Examiner states that the reasons for the rejection are set forth in the objection to the specification under paragraph 1 of the Office Action dated March 4, 1996 (hereinafter "the Office Action"). Under paragraph 1, the Examiner states that the specification does not provide support for the height of the projection being greater than the largest dimension of the flexible rear member. It is believed that the Examiner is referring to the recitation in claim 19 that "at least a portion of said flexible projections extending a distance from the central axis of said shaft [is] greater than the width of said flexible member." Applicant respectfully disagrees with the Examiner's assertion and submits that this recitation is supported by the specification.

On page 7, lines 6-8 of the specification, rivet 100 is described as having a central axis. As shown in Fig. 5, at least a portion of the flexible projections 116, for example, the apex of one of the projections, extends a distance from the central axis of rivet 100. As shown in Figs. 5 and 6, disc 118 has a width extending from the inner diameter of shaft 112 to the outermost diameter of disc 118. The term "width" is appropriate in this case since it corresponds to a single dimension relating to the actual

measurement of the flexible member itself, and not requiring the use of more than one radius to describe the dimension being claimed. Basis for the use of the term "width" may be found in the specification, for example, on pages 3, lines 25-27; page 6, lines 3 and 4; and page 7, lines 6-8. Pages 3 and 6 both refer to rear end 120 having a "widened portion" in the form of a disc. (See, e.g., disc 118, Figs. 5 and 7).

Merriam-Webster's Collegiate Dictionary defines the term "widened" under the term "widen" as meaning "to increase the *width*, scope, or extent of."[1] A copy of page 1352 of Merriam-Webster's Dictionary is attached as Exhibit A. The term "widened," found on page 3, line 26 and page 6, line 3 of the specification, corresponds to an increased width as defined in the Dictionary. The term "length" is described in relation to the central axis of rivet 100 on page 7, lines 6-8 of the specification. It is generally understood that a width is at a right angle to a length. Thus, Applicant submits that the use of the term "width" is proper in claim 19, is supported by the specification, and would be understood in the context used by one of ordinary skill in the art.

Support for the phrase "the distance between a portion of the flexible projections and the central axis being greater than the width of the flexible member" is found in the specification, for example, on page 8, lines 3-12 wherein dimensions of the rivet are provided. From this example, the width of the disc member is 0.625 mm, calculated by subtracting the radius of 0.625 mm of passageway 124 (the diameter being 1.25 mm (page 8, line 12) from the outer radius of 1.25 mm of disc 118 (the diameter being 2.5 mm (page 8, line 6)). Since a portion of at least one flexible projection 116 extends beyond the outer diameter of shaft 112 (see, e.g., Fig. 5), the distance according to the

1 Merriam-Webster's Collegiate Dictionary10th Edition; Merriam-Webster, Incorporated; Springfield, Massachusetts, U.S.A. (1999); page 1352 (emphasis added).

exemplary dimensions disclosed on page 8 between one of flexible projections 116 and the central axis would have to be at least greater than 1 mm (the radius of shaft 112; the diameter being 2 mm (page 8, line 5)). Applicant submits that the specification supports the recitation that "at least a portion of said flexible projections extending a distance from the central axis of said shaft greater than the width of said flexible member," thus overcoming the Examiner's rejection of claims 19-24 under 35 U.S.C. § 112, first paragraph.

Moreover, in the Office Action the Examiner states that the specification "does support the limitation that the distance from the top of the projection to the central axis of the shaft is greater than the diameter of the head (said another way, the sum of the radius of the shaft and the height of the projections is greater than the radius of the head)." (Page 2 of the Office Action). Applicant has submitted together with this appeal brief, an Amendment After Final amending the language of claim 19 to include the language suggested by the Examiner.

As to the last paragraph under paragraph 1 of the Office Action, Applicant submits that the reasoning stated in that paragraph is inapplicable to the present claims since the feature objected to was in claim 25, which was deleted in the Amendment filed October 30, 1995.

(ii) Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

With respect to the Examiner's rejections of claims 19-27 under 35 U.S.C. § 112, second paragraph, Applicant notes that only claims 19-24, 26, and 27 are under rejection since claim 25 was cancelled in the Amendment dated October 30, 1995. The arguments set forth above relating to the rejection of claims 19-24 under 35 U.S.C. §

112, first paragraph, are hereby incorporated by reference herein. The term "widened portion" is used to describe disc 18, 118 as seen in Figs. 1 and 5. Merriam-Webster's Collegiate Dictionary states that the term "widened" correlates with an "increased width."[2] Applicant submits that the use of the term "width" to describe a dimension extending from the inner diameter to the outer diameter of the flexible member is both proper and has basis in the specification as would be understood by one of ordinary skill in the art.

As to claim 24, the Examiner states that it is unclear how only two apexes are in the same plane "when each horizontal plane includes four projections which are spaced about the rivet's central axis." (See, last paragraph under paragraph 3 of the Office Action). Claim 24 depends from claim 23 which states that the "flexible projections are positioned in a radially staggered configuration along said shaft." Fig. 6 shows that the flexible projections are radially offset from one another providing support for the recitation that "no more than two said apexes of said flexible projections are in one plane perpendicular to the longitudinal axis of said shaft." Applicant submits that claim 24 is both clear in its language and finds support in the specification.

(iii) Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 19, 22, and 26-28 under 35 U.S.C. § 103 as being unpatentable over Warren '914.

Warren '914 discloses a surgical fastener for attaching soft tissues. (See, Warren '914, abstract). Independent claim 19 recites that "at least a portion of said flexible projections extending a distance from the central axis of said shaft [is] greater

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[2] Id.

than the width of said flexible member." Warren '914 fails to teach, suggest or show at least a portion of the flexible projections extending a distance from the central axis of the shaft that is greater than the width of the flexible member. (See, e.g., Warren '914, Fig. 1 which shows ribs 135 extending a distance from the central axis of the shaft that is less than the width of head 110).

Moreover, the Examiner admits that Warren '914 does not describe the flexibility of head 110. Independent claims 19 and 28 recite a tissue rivet being "sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted . . . ."

Applicant submits that it would not have been obvious to modify the rivet of Warren '914 to arrive at Applicant's claimed invention. Warren '914 teaches the use of a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110. (See, Warren '914, column 3, lines 40-42). Because it is known in the art that fillets are often used to reinforce a corner where two surfaces meet, it is submitted that the description of Warren '914 actually teaches away from Applicant's claimed invention.

Even assuming, *arguendo*, fillet 161 were not present, Warren '914 teaches that head 110 is repeatedly struck in order to move fastener 100 down a guide wire 400 and into the tissue. (See, Warren '914, column 5, lines 8-16; and Figs. 6-8). If head 110 of Warren '914 were modified to be sufficiently flexible so as to conform to the surface of the tissue in which the rivet is inserted as claimed by Applicant, it is submitted that inserting such a fastener as taught by Warren '914 would render the fastener unusable for its intended purpose. Applicant's claims 19 and 28 are directed to a rivet that is

capable of deforming so as to conform to the surface of the tissue in which the rivet is inserted and could not function for its intended purpose if the flexible member had to be rigid enough to withstand repeated blows on its rear surface to drive it into the tissue.

Applicant also submits that the Examiner is using impermissible hindsight in order to fashion a motivation to support the rejection. The Examiner states that the "modification would have been obvious for one of ordinary skill would have the rivet in flush contact with the tissue so that a smooth transfer surface would be formed, thereby insuring that nothing would be caught on the extending rivet head and damaged." (See, last paragraph under paragraph 5 of the Office Action). Such a motivation is not suggested in the art cited by the Examiner. In the specification, Applicant teaches a flexible member that is "sufficiently flexible so as to be able to conform to the angle of the meniscus" (page 7, lines 31-33 of the specification) which reduces irritation in the surrounding tissues. It is respectfully submitted that the Examiner gleaned the motivation used to reject the present claims over Warren '914 from Applicant's own teachings in the specification. It is therefore submitted that a *prima facie* case of obviousness has not been established.

With respect to the Examiner's rejection of claim 22 under 35 U.S.C. § 103 over Warren '914, the Examiner has not provided any grounds of rejection specific to the subject matter of claim 22. Claim 22 recites that there are at least five flexible projections. Since the Examiner has provided no grounds of rejection and/or motivation specific to claim 22, it is submitted that a *prima facie* case of obviousness has not been established. Therefore, the rejection of claim 22 under 35 U.S.C. § 103 over Warren '914 is improper and must be withdrawn.

With respect to the Examiner's rejection of claim 26 under 35 U.S.C. § 103 over Warren '914, again, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 26. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 26 under 35 U.S.C. § 103 is improper and must be withdrawn.

Even if the Examiner had provided proper grounds of rejection, claim 26 includes the recitation that the flexible member "has a greater surface area to mass ratio than said hollow shaft for permitting a higher absorption rate." Warren '914 teaches a head 110 that is thicker along the longitudinal axis of the fastener (i.e., has more mass than surface area) than the radial thickness of shank 115 (the thickness of head 110 is 0.069" (Warren '914, col. 3, line 38) and the radial thickness of shank 115 is 0.045" (Warren '914, col. 3, lines 8, 9, 46, and 47); the width or thickness of shank 115 is its diameter of 0.138" minus the internal diameter of 0.048", the result being divided by two; see also Fig. 1 which shows the thicker head portion 110. The extra thickness taught by Warren '914 is necessary to provide support for the repeated blows that the head must endure during the insertion of the fastener (Warren '914, col. 5, lines 8-16). If the head of Warren '914 were thin enough to permit a higher rate of absorption, then there would be insufficient support for its insertion according to the method as taught by Warren '914. Thus, it is submitted that Warren '914 teaches away from using a flexible member having a greater surface area to mass ratio than a hollow shaft as such a modification would render Warren '914 unsuitable for proper insertion as taught in col. 5, lines 8-16 of Warren '914.

With respect to the Examiner's rejection of claim 27 under 35 U.S.C. § 103 over Warren '914, the Examiner has failed to provide any grounds for the rejection specific to the subject matter of claim 27. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 27 under 35 U.S.C. § 103 over Warren '914 is improper and must be withdrawn.

Even if the Examiner had provided any grounds for rejection, it is submitted that Warren '914 does not teach, suggest, or disclose the subject matter of claim 27. Claim 27 is drawn to a tissue rivet with a flexible member having a smaller mass than the mass of the hollow shaft "whereby said flexible member at the rear end is absorbed prior to said hollow shaft so that the flexible member at the rear end does not separate from said hollow shaft." In Warren '914, the width or thickness of shank portion 115 is less than the thickness of head portion 110 along its longitudinal axis (as shown in the discussion pertaining to claim 26 above). If both head 110 and shank 115 are made of the same biodegradable material, then after insertion shank 115 will completely degrade before head portion 110, causing head portion 110 to separate from the rest of the inserter. The opportunity for damage of the surrounding tissue is therefore enhanced by the separate and independent movement of head 110 apart from the rest of the inserter 100. It is submitted that Warren '914 teaches away from a flexible member having a smaller mass so that it is absorbed prior to the hollow shaft as claimed by the applicant since a greater thickness of the head portion 110 of Warren '914 would be needed in order to provide support for the repeated blows that the head must endure during the insertion of the fastener (Warren '914, col. 5, lines 8-16).

In the Office Action, the Examiner rejected claims 20 and 21 under 35 U.S.C. § 103 as being unpatentable over Warren '914 in view of Bays et al. '715. Bays et al. '715 teaches a tack member 10 for repairing damaged tissue, a hollow applicator 20, and a needle 30 slidablely receivable in applicator 20 and tack member 10. (See, Bays et al. '715, column 4, line 67 through column 5, line 5). Applicator 20 has a J-shaped configuration at its forward end 21 (see Bays et al. '715, Fig. 1) which serves to restrain a grip portion 15 of the tack member (Bays et al. '715, column 5, lines 5-18). The Examiner admits that Warren '914 does not disclose the driver as claimed. (See, paragraph 6 of the Office Action).

Claim 20 is drawn to the combination of the rivet as claimed in claim 19 and a driving means comprising a rod having a tapered tip forming the same angle as the angle of the conical penetration head of the rivet. Applicant submits that one cannot combine the applicator of Bays et al. '715 with the surgical fastener of Warren '914 to arrive at Applicant's claimed invention. In paragraph 6 of the Office Action, the Examiner stated that it would have been obvious to modify the rivet of Warren '914 with the driver as taught by Bays et al. '715, "for Bays et al. '715 teaches that this driving means allows the user to apply the force necessary to correctly place the rivet within the tissue." The Federal Circuit has found that a combination is not obvious "unless the prior art suggested the desirability of [such a] modification." (See, In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). Applicant submits that the motivation supplied by the Examiner does not support the combination of the fastener of Warren '914 with the applicator of Bays et al. '715 since Warren '914 already

provides a driving means, i.e., hollow driver 600 (Fig. 7), which already achieves the motivation supplied by the Examiner.

Even assuming *arguendo*, that there was motivation to combine the fastener of Warren '914 with the applicator of Bays et al. '715, the combination teaches away from Applicant's claimed invention. As recited in independent claim 19 from which claim 20 depends, the tissue rivet comprises a flexible member "sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted." The J-configuration of the Bays et al. '715 applicator serves to restrain the head portion "against twisting or rotation about any axis extending vertically" (Bays et al. '715, column 5, lines 16 and 17). In order to serve its intended purpose, the head portion adapted to be used with the applicator of Bays et al. '715 must be sufficiently rigid enough to withstand axial movement and withstand twisting or rotation. Applicant submits that if head 110 of the Warren '914 fastener has the sufficient rigidity for use with the J-configuration of the applicator of Bays '715 (which in fact is likely for reasons already stated above), then the proposed combination would not render Applicant's claimed invention obvious since a fastener head that is rigid enough to withstand axial movement and twisting or rotation about any vertical axis cannot be fairly said to be sufficiently flexible so as to be capable of deforming to conform to an angle of insertion of the fastener into the tissue.

Under paragraph 6 of the Office Action (last three lines), the Examiner states that the length of the driver element is considered to be an obvious choice of experimentation and design. Presumably, the Examiner is referring to claim 21 which

recites that "the length of said rod from the handle to said tapered tip is the length of said rivet." Applicant disagrees with Examiner's ground of rejection. Having a length of the rod from the handle to the tapered tip be equal to the length of the rivet substantially assists in forming a smooth transition between the driving means and the conical penetration head. Forming a smooth transition decreases the likelihood of damage to surrounding tissue caused by the insertion of the rivet. Applicant submits that the Examiner is using impermissible hindsight in rejection claim 21 since the Examiner's rejection is based on knowledge imparted only from the Applicant's disclosure and not from any suggestion contained in the cited art.

In the Office Action under paragraph 7, the Examiner rejected claims 23 and 24 under 25 U.S.C. § 103 as being unpatentable over Warren '914 in view of Duncan '202. Duncan '202 teaches a fastener with spaced-apart legs adapted to be passed through tissue portions. (See, Duncan '202, abstract). One embodiment of Duncan '202 teaches a plurality of barbs 80E for engaging adjacent tissue. (See, Duncan '202, column 11, lines 21-30 and 48-55; and Figs. 8 and 9). The Examiner admits that Warren '914 does not teach radially staggered projections.

Dependent claim 23, which depends from independent claim 19, claims that the flexible projections are positioned in a radially staggered configuration along the shaft. Contrary to the Examiner's statement, Applicant submits that Duncan '202 does not disclose radially staggered projections. The projections in Duncan '202 are uniformly aligned along the radius of the legs of the fastener. The Examiner states that "Duncan teaches that by staggering the projections, the rivet will be better secured within the body." (See, last two lines under paragraph 8 of the Office Action). However, Duncan

'202 never mentions, shows or suggests any staggering of flexible projections. Since the Examiner never communicates the portions of Duncan '202 being relied upon, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 23 under 35 U.S.C. § 103 over Warren '914 in view of Duncan '202 is improper and must be withdrawn.

With respect to the Examiner's rejection of claim 24 under 35 U.S.C. § 103 over Warren '914 in view of Duncan '202, the Examiner has failed to provide any grounds and/or motivation for the rejection specific to the subject matter of claim 24. Therefore, it is submitted that a *prima facie* case of obviousness has not been established and that the rejection of claim 24 under 35 U.S.C. § 103 is improper and must be withdrawn.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: 7-22-02

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APPENDIX

19. A tissue rivet for holding two pieces of tissue together and to prevent movement of said rivet in the tissue made of a bioabsorbable material, comprising a single hollow shaft having a central longitudinal axis, said hollow shaft having a truncated conical penetration head at its front end, and a flexible member at its rear end, said flexible member having a width in at least one dimension larger than the largest width of said hollow shaft and sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted, said hollow shaft having a plurality of spaced, separate, flexible projections extending radially from said hollow shaft, at least one of said plurality of flexible projections capable of flexing toward said shaft when being inserted in the tissue, at least a portion of said flexible projections extending a distance from the central axis of said shaft greater than the width of said flexible member.

20. The rivet of claim 19 in combination with a driving means, said driving means comprising a rod having an outer diameter smaller than the inside diameter of the hollow shaft of said rivet and an upper handle portion having a diameter larger than the inside diameter of the hollow shaft of said rivet, said rod having a tapered tip, said tip forming the same angle as the angle of the conical penetration head of said rivet, whereby when the rod is fitted within the hollow shaft of the rivet, the surface of the tip

of said driving means forms a smooth transition with said conical penetration head of the rivet.

21. The combination rivet and driving means of claim 20 in which the length of said rod from the handle to said tapered tip is the length of said rivet.

22. The tissue rivet of claim 19 in which there are at least five said flexible projections.

23. The tissue rivet of claim 19 in which said flexible projections are positioned in a radially staggered configuration along said shaft.

24. The tissue rivet of claim 23 in which each of said flexible projections has an apex measured from the central longitudinal axis of said hollow shaft, in which no more than two said apexes of said flexible projections are in one plane perpendicular to the longitudinal axis of said shaft at any point along said shaft, whereby the maximum width of said rivet does not exceed the sum of said apexes to facilitate the insertion of said rivet through an opening in the tissue in which said rivet is inserted.

26. The tissue rivet of claim 19 in which said flexible member has a greater surface area to mass ratio than said hollow shaft for permitting a higher absorption rate of said bioabsorbable material of said flexible member.

27. The tissue rivet of claim 19 in which said flexible member of the rear end has a smaller mass than the mass of said hollow shaft, whereby said flexible member

at the rear end is absorbed prior to said hollow shaft so that the flexible member at the rear end does not separate from said hollow shaft.

28. A tissue rivet for holding two pieces of tissue together and to prevent movement of said rivet in the tissue made of a bioabsorbable material comprising a single hollow shaft having a central longitudinal axis, said hollow shaft having a truncated conical penetration head at its front end, and a flexible member at its rear end, said flexible member having a width in at least one dimension larger than the largest width of said hollow shaft and sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted, said hollow shaft having a plurality of spaced, separate, flexible projections extending radially from said hollow shaft.

Exhibit A

UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/354,450	12/12/94	MICHELSON G	P1093GV

EXAMINER
HANLON, E

F3M1/0304

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ART UNIT	PAPER NUMBER
3301	22

DATE MAILED: 03/04/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 10-30-95 ☑ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 19-24, 26-28 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☑ Claims 25 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 19-24, 26-28 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

Specification

1. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as now claimed. The specification does not provide support for the height of the projection being greater than the largest dimension of the flexible rear member. There is nothing in the specification which suggests that the distance that the projection extends from the shaft is greater than the diameter or the width of this rear member. The examiner understands the width to be the same as the diameter for the word width has not been defined in the specification. However, the specification does support the limitation that the distance from the top of the projection to the central axis of the shaft is greater than the diameter of the head (said another way, the sum of the radius of the shaft and the height of the projections is greater than the radius of the head). If applicant is attempting to claim the latter

limitation, the combined value of shaft radius and projection height, then applicant should amend the claims so that the relationship is clear.

Also, the limitations discussing the spacing of the projections relative to their height is considered new matter. There is nothing in the specification which fairly suggests the relationship that applicant is attempting to claim. The drawings are the only things that could be pointed to for support. However, the drawings do not support applicant's limitations for the distances are not clearly shown in the specification. Also, the drawings can not be used to support such a dimension for applicant's figures are not drawn to scale.

Claim Rejections - 35 USC § 112

2. Claims 19-24 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

3. Claims 19-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 is rejected for the term width has not been defined in the specification. Where is the width dimension measured from? Is the width the same as the diameter?

Claim 24 is rejected for what applicant is attempting to claim is still unclear. Claim 24 is rejected for it is unclear how only two apexes are in the same plane when each horizontal plane includes four projections which are spaced about the rivet's central axis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 19, 22, and 26-28 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren. Warren discloses a surgical rivet. He discloses that the rivet has a hollow shaft and a number of projections extending from said shaft. He also discloses that the rivet is made of a biodegradable material.

However, Warren does not discuss the flexibility of its rounded head.

It would have been obvious to modify the rivet of Warren so that its head was flexible enough to conform to the angle of the tissue. This modification would have been obvious for one of ordinary skill would have the rivet in flush contact with the tissue so that a smooth transfer surface would be formed, thereby insuring that nothing would be caught on the extending rivet head and damaged.

6. Claims 20 and 21 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren in view of Bays et al.

Warren discloses the rivet as discussed above. He does not disclose the driver as claimed.

Bays et al (Bays) teach the driver as discussed in the previous office action.

It would have been obvious to modify the rivet of Warren with the driver as taught by Bays. This would have been obvious for Bays teaches that his driving means allows the user to apply the force necessary to correctly place the rivet within the tissue. Applicant is to note that the lengths of his driver's elements are considered to an obvious choices of experimentation and design.

7. Claims 23 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Warren in view of Duncan.

Warren discloses the rivet as discussed above. He does not disclose the radially staggered projections as claimed.

Duncan teaches tissue rivets. He discloses that his rivets have radially staggered projections.

It would have been obvious to modify the rivet of Warren with the radially spaced projections as taught by Duncan for Duncan teaches that by staggering the projections, the rivet will be better secured within the body.

Response to Amendment

8. Applicant's arguments filed October 30, 1995 have been fully considered but they are not deemed to be persuasive. The examiner submits that the argument suggesting that Warren does not teach flexible projections is without merit for in column 7, lines 17-21, he discusses ways in which the projections can be even more flexible than originally intended.

The examiner submits that the material used by Warren is flexible enough to shape itself to a hole's angle of entry for Warren teaches that his rivet is made from the same material that applicant uses for his rivet, polyglycolic acid or polyglycolide. The examiner also submits that making a head flexible enough to contour to the surface of an entry site would have been obvious to one of ordinary skill for the contouring head would prevent injury within the body.

The examiner submits that the modification of the Bays et al driver so that the angle of attack was the same for the driver and the rivet would have been obvious for a constant angle provides smooth entry into the body, thereby reducing the trauma experienced by the body.

In response to applicant's remarks that the Duncan reference does not teach staggered projections, the examiner submits that said projections are taught. Duncan teaches that his projections are staggered about the longitudinal axis of the rivet, thus, staggered, longitudinal projections. This modification is not hindsight for Duncan teaches that his spaced projections securely retain the tissue rivet within the body.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Hanlon whose telephone number is (703) 308-2678.

MICKEY YU
PRIMARY EXAMINER
ART UNIT 331

beh
March 4, 1996

PATENT
Attorney Docket No. 101.0023-04000
Customer No. 22882
Via Express Mail Label No. ET747368123US

APPENDIX

19. A tissue rivet for holding two pieces of tissue together and to prevent movement of said rivet in the tissue made of a bioabsorbable material, comprising a single hollow shaft having a central longitudinal axis, said hollow shaft having a truncated conical penetration head at its front end, and a flexible member at its rear end, said flexible member having a width in at least one dimension larger than the largest width of said hollow shaft and sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted, said hollow shaft having a plurality of spaced, separate, flexible projections extending radially from said hollow shaft, at least one of said plurality of flexible projections capable of flexing toward said shaft when being inserted in the tissue, at least a portion of said flexible projections extending a distance from the central axis of said shaft greater than the width of said flexible member.

20. The rivet of claim 19 in combination with a driving means, said driving means comprising a rod having an outer diameter smaller than the inside diameter of the hollow shaft of said rivet and an upper handle portion having a diameter larger than the inside diameter of the hollow shaft of said rivet, said rod having a tapered tip, said tip forming the same angle as the angle of the conical penetration head of said rivet, whereby when the rod is fitted within the hollow shaft of the rivet, the surface of the tip

RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE

Attorney Docket No. 101.0023-04000
Customer No. 22882
Via Express Mail Label No. ET747368123US

Exhibit C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Gary Karlin Michelson, M.D.

Serial No.: 08/354,450 — Group Art Unit: 3301

Filed: December 12, 1994 — Examiner: D. DeMille

For: DEVICE FOR ARTHROSCOPIC MENISCAL REPAIR

BOX AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

AMENDMENT AFTER FINAL

In reply to the Final Office Action of March 4, 1996 and pursuant to 37 C.F.R. § 1.116, Applicants proposes that this application be amended as follows:

IN THE CLAIMS:

Please amend claim 19 (with the changes as shown in the attachment) to read as follows:

--19. (Twice Amended) A tissue rivet for holding two pieces of tissue together and to prevent movement of said rivet in the tissue made of a bioabsorbable material,

comprising a single hollow shaft having a central longitudinal axis, said hollow shaft having a truncated conical penetration head at its front end, and a flexible member at its rear end, said flexible member having a width in at least one dimension larger than the largest width of said hollow shaft and sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted, said hollow shaft having a plurality of spaced, separate, flexible projections extending radially from said hollow shaft, at least one of said plurality of flexible projections capable of flexing toward said shaft when being inserted in the tissue, said shaft and said flexible member each having a radius measured from the central longitudinal axis of said shaft, each of said flexible projections having a height measured from a surface of said shaft, the sum of the height of one of said flexible projections and the radius of said shaft being greater than the radius of said flexible member.--

REMARKS

Applicant has amended claim 19 to further define Applicant's claimed invention and reduce the issues for appeal. Applicant submits that the amendment to claim 19 places the claims in better form for appeal by removing the Examiner's rejection of claims 19-24 under 35 U.S.C. § 112, first paragraph since Applicant has substantially incorporated language proposed by the Examiner in the Office Action as having support in the specification. (See, paragraph 1 of the Office Action dated March 4, 1996).

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: 7-22-02

By: _____
Amedeo F. Ferraro
Registration No. 37,129
Attorney for Applicant

14500 Avion Parkway, Suite 300
Chantilly, VA 20151-1101
Telephone: (703) 679-9300
Facsimile: (703) 679-9303

CHANGES TO THE CLAIMS

19. (Twice Amended) A tissue rivet for holding two pieces of tissue together and to prevent movement of said rivet in the tissue made of a bioabsorbable material, comprising a single hollow shaft having a central longitudinal axis, said hollow shaft having a truncated conical penetration head at its front end, and a flexible member at its rear end, said flexible member having a width in at least one dimension larger than the largest width of said hollow shaft and sufficiently flexible so as to be capable of deforming so as to conform to an angle of insertion of said rivet into the tissue and capable of deforming so as to conform to the surface of the tissue in which said rivet is inserted, said hollow shaft having a plurality of spaced, separate, flexible projections extending radially from said hollow shaft, at least one of said plurality of flexible projections capable of flexing toward said shaft when being inserted in the tissue, said shaft and said flexible member each having a radius measured from the central longitudinal axis of said shaft, each of said flexible projections having a height measured from a surface of said shaft, the sum of the height of one of said flexible projections and the radius of said shaft being greater than the radius of said flexible member ~~at least a portion of said flexible projections extending a distance from the central axis of said shaft greater than the width of said flexible member~~.

UNITED STATES PATENT AND TRADEMARK OFFICE

101.0023-04

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/354,450	12/12/1994	GARY K. MICHELSON	P10936V	3041

7590 02/24/2003

MARTIN & FERRARO, LLP
114500 AVION PARKWAY, SUITE 300
CHANTILLY,, VA 20151-1101

Exhibit D

EXAMINER
DEMILLE, DANTON D

ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED BY: tmm
ON: 3-12-03
ACTION REQUIRED: reply brf

DATE REQUIRED: 4-24-03 = 2/10

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
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WASHINGTON, D.C. 20231
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 33

Application Number: 08/354,450
Filing Date: December 12, 1994
Appellant(s): MICHELSON, GARY K.

Amedeo F. Ferraro
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief granted 2 December 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct. However, the amendment filed along with the brief has been entered and overcame the 35 USC 112 second paragraph rejection of claim 19 and therefore has been withdrawn.

(4) Status of Amendments After Final

The amendment after final rejection filed on 23 July 2002 has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is not accurate and misleading because in lines 12-14 on page 3 of the brief, appellant states "At least a portion of the flexible projections 116 extending a distance from the central axis of shaft 112 greater than the width of flexible member 118 (Fig. 5)." However there is no support in the specification for such a limitation. Appellant points to figure 5 for support however, no such detail can be gleaned from the drawing. In fact if one were to draw a straight line from the apex of the flexible projections 116 from figure 6 back to the flexible member 118, it would appear that they extend the same distance. There is nothing in the written description to cover such a limitation.

On page 4, lines 10-12, appellant states "in which no more than two of the apexes of flexible projections 116 are in one plane perpendicular to the longitudinal axis of shaft 112 at any point along shaft 112 (Figs. 5 and 6)." However, there is no support in the written specification or drawings for this limitation. Appellant points to figures 5 and 6 for support however, no such details can be gleaned from these drawings. Figure 5 would appear to show the flexible projections are formed in a plurality of parallel rows. The four end flexible projections would appear to lie in the same perpendicular plane not more than just two.

On page 4, lines 15-17, appellant states that the flexible member 118 has a greater surface area to mass ratio than the hollow shaft 112 for permitting a higher absorption rate of the bioabsorbable material. Appellant relies on figure 5 for support for this claim however, no such detail can be gleaned from the drawing. The portion of the specification appellant points to merely describes the bioabsorbable composition of the overall device. There is no support for the specific ratio claimed.

Since appellant is relying patentability on these limitations it is not clear why there is no mention of these details in the written description. If these features are so important to the invention then why doesn't the specification even mention them?

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that all of the claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

101.0023-04
2/23/03 OA

Application/Control Number: 08/354,450
Art Unit: 3764

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5261914	Warren	11-1993
4976715	Bays et al.	12/1990
4548202	Duncan	10-1985

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 19-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 19, the language "the sum of the height of one of said flexible projections and the radius of said shaft being greater than the radius of said flexible member" has no support in the written specification and cannot be fairly interpreted from the drawings. Basically, the language says that the flexible projections 116 extend away from the central axis further than the flexible member 118.

As far as the drawings are concerned, drawing a straight line from the tips of the projections 116 to the tip of the flexible member 118 from any of figures 6-8 yields that they are about the same height. It cannot be ascertained from any drawing that the projections 116 extend out a further distance that the flexible member 118. Details such as these cannot be ascertained

from the drawings with any specificity. Moreover the specification does not even mention this critical feature that leads one to wonder why is the patentability hinging on this feature when it isn't described in the written description?

Appellant points to a section of the specification for support for this limitation however, appellant is mixing the numbers from a larger embodiment with the numbers of a smaller embodiment to achieve support. This is misleading and will be described in detail later.

The rejection of claim 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of the 23 July 2002 amendment. With the amendment of 23 July 2002 to claim 19, the language at the bottom of the claim has been clarified as to it's meaning thereby overcoming the 112 2nd paragraph rejections.

Claim 24 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 24 remains rejected because it is unclear what appellant is attempting to claim. Claim 24 recites that "no more than two said apexes of said flexible projections are in one plane perpendicular to the longitudinal axis of said shaft at any point along said shaft". It would appear in all of the drawings the projections all extend in the same perpendicular plane. Therefore there are always four projections in a plane perpendicular to the longitudinal axis. There is also no support in the specification for this critical feature. It is not clear how appellant can claim that no more than two projections lie in a perpendicular plane when it appears all four projections lie in the same perpendicular plane.

Claim Rejections - 35 USC § 103

Claims 19, 22 and 26-28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren. Warren discloses the same surgical rivet arrangement as that claimed by appellant. He discloses that the rivet has a hollow shaft and a number of projections extending from said shaft and the flexible member at the other end. He also discloses that the rivet is made of biodegradable material, copolymers of glycolide, the same material used by appellant. Warren also teaches that the material is intended to be resilient such that the projections deform upon insertion. Due to the fact that the rivet of Warren is made of the same material as the instant invention and that this material has to be resilient in order to perform, it would appear that rivet of Warren would comprehend the claimed resilient characteristic at least to some extent. It is not clear exactly how the claimed rivet is different from Warren's rivet however, it would have been obvious to modify the rivet of Warren as desired so that its head was flexible enough to conform to the angle of the tissue. This modification would have been obvious for one of ordinary skill to have the rivet in flush contact with the tissue so that a smooth transfer surface would be formed, thereby insuring that nothing would be caught on the extending rivet head and damaged. Making the head of screws, rivets and the like flush has always been a problem solved through routine experimentation.

Claims 20 and 21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren in view of Bays et al. Warren discloses the rivet as discussed above. He does not disclose the driver as claimed.

Bays teaches the driver as discussed in the previous office action. It would have been obvious to one of ordinary skill in the art to modify the rivet of Warren with the driver as taught

by Bays to complete the operation of installing the rivet in use. This would have been obvious for Bays teaches that his driving means allows the user to apply the force necessary to correctly place the rivet within the tissue. Appellant is to note that the lengths of his driver's elements are well within the realm of the artisan of ordinary skill and is not inventive to discover the optimum or workable ranges by routine experimentation.

Claims 23 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Warren in view of Duncan. Warren may not teach the staggered projections as claimed however Duncan teaches rivets that have radially staggered projections. It would have been obvious to one of ordinary skill in the art to modify the rivet of Warren to stagger the projections as taught by Duncan so the rivet will be better secured within the body.

(11) Response to Argument

Regarding the §112 first paragraph rejection, appellant relies on page 8 lines 3-12 for support by calculating the radius of the flexible projection and comparing it to the radius of the flexible member however, what appellant is doing is comparing two different embodiments. Lines 3-10 describe an embodiment that has a 2.0 mm diameter shaft and lines 11-16 are describe an embodiment that has a 1.25 mm diameter shaft. Appellant takes the radius of the shaft of the smaller embodiment and subtracts it from the radius of the flexible member of the larger embodiment. This gives a misleading dimension of the height of the flexible member. At the beginning of the third line from the bottom of page 7 of the brief appellant states that the diameter of the shaft is taken from page 8, line 12 of the specification and at the beginning of the second line from the bottom of page 7 of the brief appellant states that the diameter of the flexible member is taken from page 8, line 6 of the specification. In the specification page 8 one

can clearly see that line 12 is under line 11 that states "In the alternative embodiment of the present invention...." which is a smaller embodiment from the lines above line 11 which is where appellant got the dimension for the flexible member in line 6 and is the larger sized embodiment. Appellant takes the radius of the smaller rivet being 0.625 mm, half of the smaller diameter 1.25 mm, and subtracts that from the outer radius of the flexible member 118 of the larger rivet being 1.25 mm, half of the larger diameter dimension 2.5 mm. This yields a number that is not a true dimension in any embodiment. Moreover, appellant takes this false dimension 0.625 mm, which is supposed to be the height of the flexible member above the outside surface of the shaft, and compares it to the raw radius of the projections which appellant states has to be greater than 1 mm because the overall diameter of the rivet is 2 mm. The second number includes the diameter of the shaft whereas the first number subtracts the diameter of the shaft. None of these arguments make any sense.

On page 8 lines 8-14 of appellant's brief, appellant quotes the examiner to say that the projections extend a greater distance than the flexible member however, this quote is taken out of context. This quote was an attempt to clarify the §112 second paragraph problem with the language describing the height of the projections being greater than the height of the flexible member. The original language in the claim was comparing the radius of the projections to the diameter of the head which was confusing. The amendment filed with the brief has clarified this problem and is now moot.

Regarding the rejection of claim 24, appellant states that claim 24 depends on claim 23 which states that the flexible projections are staggered and points to figure 6. Yes this is true they are staggered radially about the outer surface of the shaft. They are staggered at about 90°

intervals. This has nothing to do with whether or not no more than two projections lie in a plane perpendicular to the longitudinal axis. The written description doesn't support such a claim and the drawings are not drawn to scale so the drawings don't support such a claim.

Regarding the §103 rejection of claims 19, 22 and 26-28, Warren may not teach that the projections extend a greater distance than the flexible member however, appellant's invention doesn't either and therefore Warren doesn't have to show it. Appellant can't support such a limitation and therefore Warren doesn't either.

Warren may not describe the flexibility of the head however, since appellant's invention and Warren's invention is made of the same material and that Warren states that the fastener is formed out of a resilient material it would appear that Warren's fastener would comprehend the claimed invention. It is not clear how it would differ since they are made of the same material. The projections or ribs 135 have to deform upon engagement with the tissue in the same manner as appellants. Warren teaches that another part of the fastener is flexible, appellant is merely describing how the head is also flexible. Since they are made of the same material how is the head any different from the instant invention?

However, to any extent the head of Warren is some how different from the instant invention, it would have been obvious to make it more flexible so that the head conforms to the angle of the surface of the tissue to prevent any portion of the head from extending outwardly forming a sharp edge that would be damaging to the patient. Such consideration is not new and is well within the realm of the artisan of ordinary skill.

Appellant argues that Warren uses a fillet 161 at the junction of shank portion 115 and lower surface 160 of head 110 however, there is no claim limitations precluding the presents of a

fillet. While fillets are commonly used to join the head to the shank, there is nothing in the specification that says the instant invention can't have a fillet.

Appellant argues that Warren states that the fastener has to be struck repeatedly in order to move the fastener into place however, so does appellant's. That is the purpose of appellant's driver 130. The handle 131 has a surface that mates with the head 118 to drive the fastener into the tissue. Again they operate in the same manner.

Appellant argues that the examiner has not provided any grounds of rejection for claim 22 however claim 22 falls with claim 19 because Warren clearly anticipates the at least five flexible projections in figure 9. No argument was given because it was understood that appellant could read the reference.

Regarding claim 26, the limitation that the flexible member "has a greater surface area to mass ratio than said hollow shaft for permitting a higher absorption rate" is not supported by appellant's disclosure and therefore Warren doesn't have to show it. Appellant argues how Warren's fastener doesn't teach the recited limitation however appellant hasn't provided any support of how the specification of the instant invention supports such a limitation. The same would apply to claim 27 and the limitation "whereby said flexible member at the rear end is absorbed prior to said hollow shaft so that the flexible member at the rear end does not separate from said hollow shaft."

Regarding claims 20 and 21 and the application of Bays et al., it is not clear how appellant can disregard the teaching of Bays. Warren teaches that the fastener has to be driven in place but fails to show how the fastener is driven in place. Bays provides the device in which to drive the fastener in place. The driver has the shaft that would fit within the hollow shaft of the

fastener and be driven in place just the same. While Bays includes the J-configuration to help hold the fastener to the driver, there are no claim limitations that somehow preclude this additional feature. The J-configuration could just as easily be applied to the Warren fastener.

Regarding claim 21 and the limitation "the length of said rod from the handle to said tapered tip is the length of said rivet", Bays would appear to comprehend this language as shown in figure 2. The function of forming a smooth transition between the driving means and the conical penetration head is still achieved by Bays. Any difference is a matter of degree. The intended purpose of the pointed end of the driver is to aid the penetration of the driver and fastener through body tissue. The purpose of the pointed end is to provide a smooth transition for the fastener. If there is any difference between the length of the shaft and the length of the fastener is a matter of degree and an obvious provision to one of ordinary skill in the art.

Regarding claim 23, it is not clear how appellant can disregard the teaching of Duncan. Duncan teaches the continuous barbs in figures 1-7 and shows the discontinuous barbs in figures 8+. Warren teaches continuous barbs just as Duncan does in figures 1-7 but as taught by Duncan in figures 8+ discontinuous barbs are an obvious equivalent alternative. Appellant argues that Duncan's barbs are not radially staggered. That they are uniformly aligned along the radius of the legs of the fastener. That may be true too. The barbs of Duncan are radially staggered 90° just as appellant's barbs are radially staggered 90° and are uniformly aligned just as appellant's. It is not clear how they are different.

Regarding claim 24, the limitation that no more than two projections are in one plane perpendicular to the longitudinal axis of the shaft is not supported by the specification of the

instant invention and therefore the prior art doesn't have to show it. Appellant can't make the claim and therefore the prior art doesn't have to make it either.

Conclusion

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Danton DeMille
Primary Examiner
Art Unit 3764

ddd
February 21, 2003

Conferees
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UNITED STATES
PATENT AND
TRADEMARK OFFICE

Commissioner for Patents
Washington, DC 20231
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FEB 20 2003

Dear Patent Business Customer:

The United States Patent and Trademark Office ("Office") is now permitting and encouraging applicants to voluntarily submit amendments in a revised format as set forth in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, ____ *Off. Gaz. Pat. Office* __ (February 25, 2003), currently available on the USPTO web site at **http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm**. The revised format permits amendments to the specification and claims to be made in a single marked-up version; the requirement for a clean version is eliminated. Attached, you will find a flyer with information and instructions regarding the procedures to be used to comply with the revised format. The flyers are being inserted with out-going Office actions mailed during the period of February 20, 2003 - March 31, 2003.

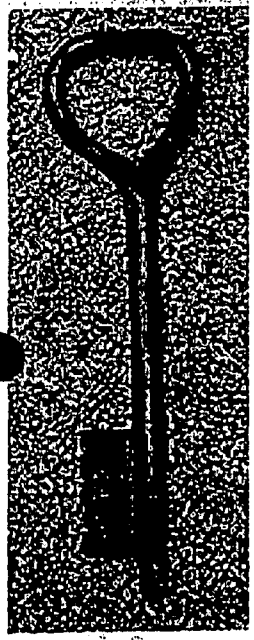
The revised amendment format is essentially the same as the amendment format for the specification, claims, and drawings that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. This proposed revision and others necessary to facilitate a gradual transition to the use of an Electronic File Wrapper (EFW) will be set forth in a Notice of Proposed Rule making (NPR), expected to be published by March 2003. After consideration of public comments, the Office anticipates adopting a revision to § 1.121, following publication of a Notice of Final Rule making (NFR), expected by June 2003, at which point compliance with revised § 1.121 will be mandatory.

The Office will continue to accept your amendment submissions in the revised format during the voluntary period, which will extend up to the effective date of final revisions to § 1.121. The Office also encourages your feedback on the proposed revised amendment format and other changes set forth in the NPR, expected to be published by March 2003.

For assistance: Any questions regarding the submission of amendments pursuant to the revised practice should be directed to Office of Patent Legal Administration (OPLA), Legal Advisors Elizabeth Dougherty (**Elizabeth.Dougherty@uspto.gov**), Gena Jones (**Eugenia.Jones@uspto.gov**) or Joe Narcavage (**Joseph.Narcavage@uspto.gov**). Alternately, you may send e-mail to "Patent Practice", the OPLA e-mail address that has been established for receiving queries and questions about patent practice and procedures or telephone OPLA at (703) 305-1616.

Nicholas P. Godici
Commissioner for Patents

Attachment: Flyer entitled: *Revised Notice* AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT*



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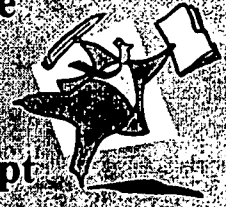

(4) A claim may be canceled by merely providing an instruction to cancel. Listing a claim as canceled will constitute an instruction to cancel. Any claims added by amendment must be indicated as (new) and shall not be underlined.

(5) All of the claims in each amendment paper must be presented in ascending numerical order. Consecutive canceled or withdrawn claims may be aggregated into one statement (e.g., Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word "claim" before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (withdrawn)

Claim 7 (previously amended): A bucket with a handle.

Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 9 (withdrawn)

Claim 10 (original): The bucket of claim 8 with a wooden handle.

Claim 11 (canceled)

Claim 12 (re-presented – formerly dependent claim 11) A black bucket with a wooden handle.

Claim 13 (previously added): A bucket having a circumferential upper lip.

Claim 14 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:

Amendments to the specification must be made by presenting a replacement paragraph or section marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per current 37 CFR 1.125.

C) Amendments to drawing figures:

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with § 1.84. An explanation of the changes made must be presented in the remarks section of the amendment. Any replacement drawing sheet must include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing should **not** be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Any questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to the following legal advisors in the Office of Patent Legal Administration (OPLA): Elizabeth Dougherty (Elizabeth.Dougherty@uspto.gov), Gena Jones (Eugenia.Jones@uspto.gov) or Joe Narcavage (Joseph.Narcavage@uspto.gov). For information on the waiver or legal aspects of the prototype, please contact Jay Lucas (Jay.Lucas@uspto.gov), Senior Legal Advisor (PCTLA) or Rob Clarke (Robert.Clarke@uspto.gov), Senior Legal Advisor (OPLA). Alternatively, further information may be obtained by calling OPLA at (703) 305-1616.

* Revised Notice: See Sec. B) for changes relating to substitute specifications, and Sec. C) for changes on replacement drawing practice.